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Učestalost pojedinih postupaka izvananalitičke faze laboratorijske dijagnostike u Hrvatskoj - presječno anketno istraživanje

Self reported routines and procedures for the extra-analytical phase of laboratory practice in Croatia - cross-sectional survey study

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Sažetak

Uvod: Izvananalitička faza izvor je najvećeg djela pogriješaka u laboratorijskoj praksi. Presječno istraživanje temeljeno na upitniku o učestalosti pojedinih postupaka izvananalitičke faze laboratorijskog rada učinjeno je među članovima Hrvatske komore medicinskih biokemičara (HKMB) u svrhu procjene stanja.

Materijali i metode: Anonimnim upitnikom s 20 pitanja zatvorenog tipa ispitana je učestalost (Likertova ljestvica; nikad = 1, rijetko = 2, često = 3 i uvijek = 4) pojedinih postupaka izvananalitičke faze laboratorijske dijagnostike među članovima HKMB (N = 538). Odgovori na pitanja izraženi su prosječnom ocjenom 1,00–4,00. Pitanja su nadalje podijeljena u tri skupine te je za svaku izračunata prosječna ocjena: kriteriji prihvatljivosti uzorka, postupci vađenja krvi, izvještavanje nalaza te pitanje o bilježenju nesukladnosti u radu.

Rezultati: Udio ispitanika koji su odgovorili na anketu bio je 27%. Od ukupnog broja ispitanika 93% su žene, 58% diplomirani inženjeri medicinske biokemije i 42% specijalisti medicinske biokemije. Prikupljeni su podatci o vrsti ustanove u kojoj djeluje laboratorij te o informatičkoj pismenosti ispitanika.

Prosječna ocjena svih postupaka (aritmetička sredina ± standardna devijacija) iznosila je $3,12 \pm 0,38$. Nema statistički značajne razlike s obzirom na vrstu ustanove, stupanj usavršavanja i informatičku pismenost niti povezanosti prosječne ocjene i dobi. Ocjena postupaka vađenja krvi ($2,83 \pm 0,46$) najniža je od ocjena triju skupina pitanja ($P < 0,001$), slijedi ocjena izvještavanja rezultata ($3,19 \pm 0,48$) te ocjena kriterija prihvatljivosti uzoraka ($3,33 \pm 0,49$). Nesukladnosti u radu nikad ili rijetko bilježi 21% ispitanika, a često i uvijek 79%.

Zaključci: Rezultati upućuju na žurnu potrebu za unaprjeđenjem postupaka izvananalitičke faze laboratorijske dijagnostike, napose postupaka u svezi s vađenjem krvi. Za postizanje visokih standarda kvalitete nužna je intenzivna izobrazba sveg osoblja uključenog u sve faze laboratorijske dijagnostike.

Glavne riječi: medicinsko-biokemijska analiza; izvananalitička faza; kvaliteta zdravstvene zaštite; anketni upitnik

Abstract

Introduction: Extra-analytical phase is the source of most of the errors in laboratory practice. A cross-sectional survey study was performed among members of Croatian Chamber of Medical Biochemists (CCMB) aimed to investigate the status of extra-analytical phase in Croatia.

Materials and methods: Results were collected from members of CCMB (N = 538) using anonymous questionnaire with 20 Likert scaled questions testing self-reported frequency (never = 1, rarely = 2, often = 3, always = 4) of procedures of the pre-analytical phase. Answers were expressed as average score ranging from 1.00 to 4.00 for all questions. Questions were further divided in three groups, which average score was calculated accordingly: criteria of acceptance of sample, procedures of phlebotomy, test results reporting. Question on recording of nonconformities was separately evaluated.

Results: The response rate was 27%. Subject were 93% women, 58% medical biochemists with master degree and 42% specialist in medical biochemistry. Type of institution and informatics skills were also recorded.

The average overall score was (mean ± standard deviation) 3.12 ± 0.38 . There was no difference regarding type of laboratory institution, professional degree or computer skills and no correlation between score and age. Procedures of phlebotomy score (2.83 ± 0.46) achieved the lowest ($P < 0.001$) out of the three scores calculated (criteria of acceptance of sample: 3.33 ± 0.49 ; reporting of results 3.19 ± 0.48). Twenty one percent of participants never or rarely record nonconformities, whereas 79% often or always do.

Conclusion: Results clearly highlight the urgent need for improving activities in the extra-analytical phase, especially phlebotomy procedures. Reinforced education of all the personnel involved, appropriate recording and monitoring of extra-analytical phase is necessary to reach high quality standards.

Keywords: clinical chemistry tests; extra-analytical phase; quality of health care; questionnaire

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Uvod

Svakodnevni je laboratorijski rad dio cjelokupne obrade bolesnika i sastoji se od niza složenih procesa koji za cilj imaju izdavanje nalaza značajnih i ključnih za donošenje medicinskih odluka (1). Kako laboratorijske analize svake godine postaju sve brojnije i složenije, nužno je udio pogrešaka svesti na najmanju moguću mjeru. Procjenjuje se kako je 0,1 do 9,3% svih izdanih laboratorijskih nalaza pogrešno (2,3). Proces laboratorijske obrade uzoraka tradicionalno se može podijeliti u tri faze; prijeanalitičku, analitičku i poslijeanalitičku fazu. Razvoj tehnologije, automatizacija i kontrola analitičkog dijela laboratorijskog rada značajno su smanjili udio pogrešaka koje se dogode u analitičkoj fazi (4,5). Najveći broj pogrešaka u laboratorijskom radu dogodi upravo u izvananalitičkoj fazi (3-9). Procjenjuje se kako je udio pogrešaka u analitičkoj fazi rada 13%, u prijeanalitičkoj 46-68%, a u poslijeanalitičkoj fazi 18-47% od svih pogrešaka (3-9). Upravo je to razlog zašto se u posljednje vrijeme sve veća pažnja pridaje unaprjeđenju kvalitete izvananalitičke faze laboratorijskog rada. S obzirom kako su postupci izvananalitičke faze nadišli isključivo područje rada laboratorija, Međunarodna organizacija za standardizaciju (engl. *International Organization for Standardization*, ISO) preporučila je široku definiciju pojma „laboratorijska pogreška“ koja se, shodno tome, odnosi na svaku „nesukladnost“ koja se može dogoditi u bilo kojoj fazi zdravstvene zaštite koja podrazumijeva rad s laboratorijskim nalazima, od zahtjeva za pojedinim pretragama, izvještavanja nalaza, njihova tumačenja pa do medicinskih postupaka poduzetih s obzirom na laboratorijski nalaz (10).

Rad laboratorija u Republici Hrvatskoj, prema Zakonu o medicinsko-biokemijskoj djelatnosti, organiziraju, nadziru i njime upravljaju diplomirani inženjeri medicinske biokemije kojima Hrvatska komora medicinskih biokemičara (HKMB) nakon položenog stručnog ispita izdaje odobrenje za samostalan rad. Daljnje stručno usavršavanje ide ka specijalizaciji i užoj specijalizaciji, kao višim stupnjevima odgovornosti u vođenju i organiziranju rada laboratorija.

Medicinski biokemičar obavezan je nadzirati svakodnevno sve faze laboratorijske dijagnostike u laboratoriju, napose provođenje unutrašnje kontrole kvalitete te sudjelovati u obveznom nacionalnom programu vanjske kontrole kvalitete analitičke faze koju provodi i nadzire Hrvatsko društvo medicinskih biokemičara (HDMB). Vanjska kontrola izvananalitičke faze rada za sada se ne provodi sustavno na nacionalnoj razini, no zbog sve izraženije potrebe za usklađivanjem sa standardima dobre laboratorijske prakse načinjena je priprema za uvođenje nacionalne vanjske kontrole poslijeanalitičke faze po uzoru na slične međunarodne programe. Postupak akreditacije u zdravstvenoj zaštiti također se priprema na nacionalnoj razini i važan je dio politike budućeg razvoja zdravstvene zaštite u Hr-

Introduction

Daily laboratory activity is an essential part of the comprehensive patient care, and consists of various actions that should be optimized and standardized to provide laboratory reports that might be ultimately useful for the clinical decision making (1). As the number and complexity of laboratory analyses are constantly increasing, it is essential that laboratory errors are reduced to the least possible rate. It has been estimated that 0.1 to 9.3% of all laboratory reports might contain errors (2,3). Laboratory diagnostics is traditionally divided into three phases, which are pre-analytical, analytical and post-analytical. Development of technology, automatization and quality control of analytical processes has contributed to reduce significantly the rate of errors in the analytical phase (4,5). Nevertheless, potential errors still can arise from the extra-analytical phase (3-9). It is estimated that out of all errors in laboratory daily activity, 13% come from analytical, 46-68% from pre-analytical and 18-47% from post-analytical procedures (3,9), so that major focus should be placed to improve extra-analytical phase quality. Since the problem of diagnostic errors overcomes laboratory area, the International Organization for Standardization (ISO) has proposed a broader definition of the term “laboratory error”, which is now referred to as any “nonconformity” which can occur in every process of the total testing process, from test request to analysis reporting, result interpretation and medical actions undertaken according to test results (10).

According to the Croatian Law, laboratory routine activity has to be supervised and controlled by medical biochemists having at least master's degree and who have passed state exam and received license for individual activity as issued by the Croatian Chamber of Medical Biochemists (CCMB). Further professional qualification is gained through specialization which gives credibility for higher ranking responsibilities in governing and organizing laboratory activity.

Medical biochemist is obliged to control all phases of daily laboratory routine, in particular those concerning internal quality control (IQC), and to participate in mandatory program of external quality assessment (EQA) of the analytical phase, which is run and supervised by the Croatian Society of Medical Biochemists (CSMB). The EQA of extra-analytical phases is however not mandatory, as in some other countries. In order to follow new trends of good laboratory practice, an initiative for pre-analytical and post-analytical quality control implementation has been designed at national level. The process of accreditation in health care is also being prepared at national level and has become an important part of healthcare development policy in Croatia. Accreditation according to international standards is still neither obligatory nor

vatskoj. Akreditacija laboratorija prema međunarodno prihvaćenim normama nije obavezna niti je propisana zakonom u Republici Hrvatskoj, međutim postoje preporuke i naputci Hrvatske komore medicinskih biokemičara (HKMB) za standardizaciju postupaka u laboratorijskom radu. Mnogi laboratoriji u Hrvatskoj planiraju započeti postupak pripreme za akreditaciju u kratkom vremenu. Preduvjet je složenom i zahtjevnom procesu akreditacije raščlaniti i prepoznati kritična mjesta u laboratorijskom radu, sustavno pratiti sve laboratorijske procese s ciljem podizanja ukupne kvalitete laboratorijskog rada.

Presječno istraživanje trenutnog stanja kvalitete i postupaka izvananalitičke faze laboratorijske dijagnostike učinjeno je provođenjem ankete među članovima HKMB. Glavni cilj rada bio je utvrditi i uputiti na kritične točke u izvananalitičkoj fazi laboratorijskog rada tj. utvrditi područja koja zahtijevaju unaprjeđenje i brzu intervenciju. Istraživanje se temelji na vlastitoj procjeni ispitanika odgovornih za rad u laboratoriju o učestalosti pojedinih postupaka izvananalitičke faze. Također smo željeli utvrditi postoji li povezanost kvalitete izvananalitičke faze i vrste ustanove u kojoj laboratorij djeluje, stupnja profesionalnog usavršavanja i informatičke pismenosti ispitanika odgovornih za upravljanje i nadzor nad laboratorijskim radom.

Materijali i metode

Upitnik

Anonimni upitnik s ponuđenim odgovorima, koji sadrži 20 tvrdnji koje opisuju postupke izvananalitičke faze laboratorijske dijagnostike odaslan je na adrese svih članova sadržanih u bazi podataka HKMB u travnju 2009. godine. Upitnikom su prikupljeni i podatci o vrsti institucije u kojoj se laboratorij nalazi, dob, spol, stručna sprema te stupanj informatičke pismenosti ispitanika.

Tvrdnje u upitniku opisuju pojedine postupke izvananalitičke faze, a ispitanicima je ponuđeno da odgovore koliko se često u laboratorijskom radu njihovih laboratorija opisani postupci provode. Ponuđeni su odgovori: nikad, rijetko, često i uvijek, a odgovorima su dodijeljene ocjene sukladno Likertovoj ljestvice (nikad = 1, rijetko = 2, često = 3 i uvijek = 4). Pet tvrdnji u kojima su opisani nepoželjni postupci, rekodirane su tj. ocijenjene obrnutim redoslijedom (nikad = 4, rijetko = 3, često = 2 i uvijek = 1). Na taj način veća prosječna ocjena predstavlja veću kvalitetu rada u izvananalitičkoj fazi. Pouzdanost upitnika procijenjena je s pomoći koeficijenta Cronbach alfa koji iznosi $\alpha = 0,75$, što upućuje na visoku pouzdanost. Izračunata je prosječna ocjena za svakog ispitanika, a vrijednosti su uspoređene među skupinama ovisno o tipu ustanove, informatičkoj pismenosti i stupnju stručne sprema.

S obzirom kako su tvrdnje podijeljene u tri tematske podskupine, osim ukupne prosječne ocjene na sva pitanja,

defined by Croatian law for medical laboratories. There are however guidelines and recommendations for standardization issued by the Croatian Chamber of Medical Biochemists (CCMB). A variety of laboratories in Croatia have a plan to start accreditation process in a short time. As such, it becomes essential to identify critical points in laboratory activity and to systematically monitor all laboratory processes aimed to raise the global quality and to prepare for administratively demanding process of accreditation.

A cross-sectional survey study was therefore performed among members of CCMB, with the aim to investigate the status of the extra-analytical phase in Croatia. The leading objective was to detect and target the most critical points of the extra-analytical phase. The study was based on self-reported evaluation on frequency of some procedures concerning the extra-analytical phase, and was administered to personnel responsible of laboratory activity. The main results are aimed to identify those procedures needing further improvement and rapid intervention. An additional aim was to identify potential associations between self reported extra-analytical quality of laboratory activity and type of facility, degree of professional qualification and informatics skills of those responsible of laboratory management.

Materials and methods

Questionnaire

An anonymous questionnaire, consisting of 20 closed questions describing procedures of extra-analytical phase of laboratory diagnostics, was sent by regular mail to all members of CCMB in April 2009. Participants were identified using the database of the CCMB. Data on type of the laboratory (e.g., institution), age, gender, professional qualification and informatics skills were also collected.

The questions were designed as statements describing laboratory procedures and answer were offered as frequency of particular procedure performed in participant's laboratory on a four grade Likert scale, graded as 1 (never), 2 (rarely), 3 (often) and 4 (always). Negative statements (5 questions) were recoded (graded 4 for "never" to 1 for "always" respectively). As such, higher score represents higher quality of extra-analytical phase laboratory procedures. The reliability of the questionnaire was determined by Cronbach's alpha coefficient ($\alpha = 0.75$), which is globally acceptable. Results were calculated as an average grade (e.g. score for each participant), and compared between groups.

Along with the overall score concerning all questions, three more scores were calculated. The questions were also divided in three groups, including questions considering criteria of sample acceptance (6 items), questio-

TABLICA 1. Raspodjela odgovora medicinskih biokemičara u Hrvatskoj o učestalosti pojedinih postupaka izvananalitičke faze laboratorijske dijagnostike.

TABLE 1. Distribution of answers regarding occurrence of procedures of extra-analytical phase of laboratory diagnostics among medical biochemists in Croatia.

Question	N	Never (%)	Rarely (%)	Often (%)	Always (%)	Pitanja
Questions on criteria of sample acceptance						Kriteriji prihvaćanja uzorka
*Already coagulated samples are centrifuged shorter than required.	143	64	26	8	2	*Uzorci krvi za dobivanje seruma, koji su očigledno dobro zgrušani, centrifugirat će se kraće od propisanog vremena.
The sample for analysis will not be accepted, unless the tube containing anticoagulant is filled up to the mark.	143	4	26	20	50	Ukoliko epruveta s antikoagulansom nije ispunjena uzorkom krvi do oznake, ne uzima se u analizu.
*If potassium concentration in a slightly hemolytic serum is normal, new blood sampling will not be requested.	143	29	29	24	18	*Ukoliko je koncentracija kalija u blago hemolitičnom serumu normalna, ne će se tražiti ponovno vađenje.
Blood samples for serum are centrifuged at least 10 minutes at 3500 rpm.	144	4	0	9	87	Uzorke pune krvi za serum centrifugira se najmanje na 3500 okretaja u trajanju najkraće 10 minuta.
*Complete blood cells count from a slightly coagulated sample will be performed carefully observing that the coagulum is not aspirated.	140	84	9	2	5	*Iz uzorka koji je blago zgrušan učinit će se kompletnu krvnu sliku (KKS), pazeci da instrument ne aspirira ugrušak.
If the samples for the potassium measurement are even slightly hemolytic, new sampling will be requested.	142	8	21	24	47	Za uzorke i s najmanjom vidljivom hemolizom u kojima je potrebno odrediti koncentraciju kalija, zatražit će se ponovno vađenje.
Questions on procedures of phlebotomy						Postupci vađenja krvi
Prior to sampling, patient is asked what was his/her name.	143	2	3	15	80	Prilikom vađenja krvi, bolesnika se pita kako se zove.
Blood sampling is done according to the following tube cap color order: yellow or red, blue, green, purple and grey.	134	6	16	30	48	Prilikom vađenja krvi, vadi se u epruvete sljedećim redom s obzirom na boju čepa: žuti ili crveni (serum, bez aditiva), plavi, zeleni, ljubičasti, sivi.
The exact sampling time is recorded.	140	18	13	29	40	Prilikom vađenja krvi, bilježi se točno vrijeme vađenja krvi.
The patient's identity is verified with picture-based documents prior to sampling.	139	67	19	4	10	Prilikom vađenja krvi, provjerava se identitet bolesnika odgovarajućim dokumentom sa slikom.
*If patient is coming from distant destination, after an overnight fast, at 11 am for routine lab analysis the blood sample will be accepted.	142	7	30	34	29	*Bolesnicima koji dolaze izdaleka izvadi se krv za rutinske biokemijske i hematološke pretrage i u 11 sati ujutro ukoliko su natašte.
The tourniquet on the patient's arm is kept no longer than 1 minute.	141	2	10	35	53	Podveza ruke bolesnika tijekom vađenja ne drži se dulje od jedne minute.
Questions on reporting of results						Izveštavanje nalaza
If testing is done from the lypemic sample, it is noted on the report.	143	0	4	13	83	Zapisuje se na nalaz, ukoliko je serum lipemičan.
The sample type for glucose concentration measurement is noted on the report (serum, plasma, capillary blood).	141	25	12	13	50	Zapisuje se na nalaz vrstu uzorka iz kojeg je izmjerena koncentracija glukoze (serum, plazma, kapilarna krv).
*If the urine strip test is positive for blood and no erythrocytes are found in the sediment, the urine strip test result will be corrected into negative.	142	59	15	8	18	*Ukoliko je krv u mokraći test trakom blago pozitivna, a u sedimentu nema eritrocita, ispraviti će se nalaz test trake u negativan.
The requesting physician is notified about the critical values of the report.	144	1	2	18	79	O kritičnim (jako lošim) nalazima obavještava se telefonom odjel (liječnika) koji je pretragu zatražio.
The sample for the analysis, even if it is not collected after an overnight fast, will be accepted, but that will be noted on the report.	142	13	42	18	27	Bolesniku koji nije natašte izvadit će se krv i zabilježiti to na nalaz.
Reports delivered by phone to the requesting physician/nurse will be properly recorded.	139	25	15	18	42	Evidencija o nalazima koje se javi (pročita) telefonom, vodi se u za to namijenjenim obrascima/bilježnicama.
If serum is icteric, it will be noted on the report.	144	6	11	27	56	Ukoliko je serum ikteričan, taj se podatak zapisuje na nalaz.
Question on recording of nonconformities						Bilježenje nesukladnosti
All nonconformities are properly recorded.	141	6	16	32	46	Nezgode, incidente i odstupanja od propisanog načina rada zapisuje se u za to namijenjene obrasce/bilježnice.
* Answers to these questions were recoded for the purpose of score calculation as 4 for "never" to 1 for "always" while all other questions were coded as 1 for "never" to 4 for "always". That way higher score reflects more appropriate procedures.						

izračunate su pojedinačne prosječne ocjene za svaku od tri podskupine. Tvrdnje su podijeljena u tri skupine kako slijedi: 6 tvrdnji opisuje postupke koji se tiču kriterija prihvatljivosti uzoraka; 6 tvrdnji opisuje postupke prilikom vađenja krvi; 7 tvrdnji opisuje postupke izvještavanja nalaza. Pitanje o učestalosti bilježenja nesukladnosti promatrano je samostalno (Tablica 1.).

Statistička analiza

Rezultati su prikazani brojem i udjelom za kategoričke varijable te aritmetičkom sredinom i standardnom devijacijom za prosječne ocjene. Razlika u vrijednosti prosječne ocjene između dviju skupina izračunata je t-testom za nezavisne uzorke, a ANOVA testom između triju ili više skupina. Ukoliko je pronađena statistički značajna razlika između triju ili više skupina, *post-hoc* testom (Student-Newman-Keuls *post-hoc* test) je ispitana razlika među pojedinim skupinama. Povezanost dobi i prosječne ocjene ispitana je Pearsonovom korelacijom. Vrijednost P manja od 0,05 smatrana je statistički značajnom.

Statistička raščlamba učinjena je s pomoću računalne programske potpore MedCalc statistical software inačica 10.0.1.0. (MedCalc, Mariakerke, Belgija); licenca Katedre za medicinsku informatiku Medicinskog fakulteta Sveučilišta u Rijeci.

Rezultati

Od ukupno 538 članova HKMB, njih 144 (27%) ispunilo je upitnik. Ispitanici su 93% žene, prosječne dobi (medijan) 47 godina, u rasponu dobi od 26 do 65 godina. Od ukupnog broja ispitanika koji su odgovorili na upitnik, 58% su inženjeri medicinske biokemije, a 42% specijalisti medicinske biokemije. U laboratorijima primarne zdravstvene zaštite radi 40% ispitanika, 15% u laboratorijima općih bolnica, 13% u laboratorijima specijalnih bolnica, 12% u laboratorijima kliničkih bolnica, 13% u laboratorijima kliničkih bolničkih centara i 7% u privatnim laboratorijima. S obzirom na informatičku pismenost, 38% ispitanika ocijenilo je svoje vještine srednjima, a 62% dobrima.

Raspodjela odgovora o učestalosti postupaka prikazana je u tablici 1. Ukupna prosječna ocjena svih tvrdnji izračunata s obzirom na četiri stupanjku Likertovu ljestvicu, a nakon rekodiranja negativnih tvrdnji (označenih zvjezdicom, tablica 1.), iznosi (aritmetička sredina \pm standardna devijacija) $3,12 \pm 0,38$. Nije pronađena statistički značajna razlika s obzirom na vrstu ustanove ($P = 0,225$), stručnu spremu ($P = 0,090$) i informatičku pismenost ($P = 0,158$) (Tablica 2.). Ne postoji povezanost dobi i prosječne ocjene svih pitanja ($r = 0,21$; $P = 0,011$).

S obzirom kako su tvrdnje podijeljene u tri podskupine, prosječna ocjena tvrdnji za svaku od podskupina izračunata je i iznosi: $3,33 \pm 0,49$ za kriterije prihvaćanja uzorka,

ns considering procedures of phlebotomy (6 items) and questions considering reporting of results (7 items). The corresponding scores were calculated respectively. The question regarding the practice of recording nonconformities was evaluated separately (Table 1).

Statistical analysis

Results are presented as numbers and percentages for frequencies and as mean and standard deviation for scores common for data concerning grades. The difference in average score between two groups was calculated using independent sample t-test and ANOVA between three or more groups, followed by Student-Newman-Keuls post-hoc test to find out differences in between groups. Correlation between age and average score were assessed by calculating Pearson's correlation coefficient. P value less than 0.05 was considered significant for all statistical tests.

All statistical analyses were performed using MedCalc statistical software version 10.0.1.0. (MedCalc, Mariakerke, Belgium) licensed to Department of Medical Informatics, Rijeka University School of Medicine.

Results

Out of the 538 members of CCMB, 144 (27%) completed the questionnaire; 93% of them were women; the median age was 47 years and ranged from 26 to 65 years. There were 58% medical biochemists with master degree, and 42% specialist of medical biochemistry. Out of all subjects, 40% worked in primary care laboratories, 15% in laboratories of general hospital, 13% in laboratories of specialized hospital (e.g. psychiatric, rehabilitation, cardio-surgical hospital, etc), 12% of clinical hospital's laboratories, 13% in laboratories of university hospital and 7% in private laboratories. As regards the informatics skills, 38% of participants self-reported medium and 62% good skills.

The distribution of the answers to the questions is shown in table 1. The overall score was calculated according to four grade Likert scale after recoding of negative statements (table 1, marked with asterisk) and mean \pm standard deviation (SD) of overall score was 3.12 ± 0.38 . There was no statistically significant difference between groups considering type of facility ($P = 0.225$), professional qualification ($P = 0.090$) or informatics skills ($P = 0.158$) (Table 2). There was also no correlation between age and overall score ($r = 0.21$, $P = 0.011$).

As questions were divided in three groups, the score for each group were calculated as follows (mean \pm SD): 3.33 ± 0.49 for questions on criteria of sample acceptance; 2.83 ± 0.46 for questions on procedures of phlebotomy and 3.19 ± 0.48 for questions on results reporting. All three groups significantly differ from each other ($P < 0.001$), the

TABLICA 2. Usporedba ukupne ocjene svih postupaka, s obzirom na vrst ustanove u kojima ispitanici rade, njihovu stručnu spremu i informatičku pismenost.

TABLE 2. Comparison of overall score obtained through questionnaire regarding participants from different type of institution, professional qualification and their informatics skills.

Characteristics of participants		N (%)	Overall score $\bar{x} \pm SD$	Statistics
Type of institution	Primary health care	57 (40)	3.17 \pm 0.39	F = 1.41 P = 0.225
	General hospital	21 (15)	2.94 \pm 0.42	
	Specialized hospital	19 (13)	3.15 \pm 0.37	
	Clinical hospital	17 (12)	3.07 \pm 0.36	
	University hospital	19 (13)	3.16 \pm 0.36	
	Private laboratories	10 (7)	3.22 \pm 0.28	
Professional qualification	M.Sc.	83 (58)	3.08 \pm 0.38	t = 1.71 P = 0.090
	Specialists	61 (42)	3.19 \pm 0.37	
Informatics skills	Good	89 (62)	3.15 \pm 0.37	t = -1.42 P = 0.158
	Medium	54 (38)	3.06 \pm 0.38	

2,83 \pm 0,46 za postupke vađenja krvi te 3,19 \pm 0,48 za postupke izvještavanja nalaza. Prosječna ocjena postupaka pojedinih skupina međusobno se statistički značajno razlikuje ($P < 0,001$) s najnižom ocjenom postupaka vađenja krvi (Tablica 3.).

Ispitanici iz različitih vrsta ustanova u kojima njihovi laboratoriji djeluju ne razlikuju se u prosječnoj ocjeni kriterija prihvaćanja uzorka i izvještavanja rezultata, međutim, razlikuju se ocjene postupaka vađenja krvi ($P = 0,018$). Ispitanici koji rade u privatnim laboratorijima imaju značajno veću prosječnu ocjenu postupaka vađenja krvi (3,20 \pm 0,37) od ispitanika iz laboratorija općih (2,66 \pm 0,34) i kliničkih (2,64 \pm 0,31) bolnica (Tablica 3.).

Ocjena kriterija prihvatljivosti uzoraka značajno je niža u skupini inženjera medicinske biokemije nego u skupini specijalista medicinske biokemije (3,26 \pm 0,46 naspram 3,43 \pm 0,51, $P = 0,039$) (Tablica 3.).

Niti u jednoj od izračunatih prosječnih ocjena nije pronađena razlika između ispitanika s različitim stupnjem poznavanja rada na računalu. 22% ispitanika ne zapisuje nikad ili rijetko incidente i odstupanja od propisanog načina rada (nesukladnosti) u za to namijenjene obrasce, dok 78% ispitanika to čini često ili uvijek (Tablica 1.).

Rasprava

Ukupna prosječna ocjena 3,12 \pm 0,38 na ljestvici od 1 do 4 može se smatrati pokazateljem osrednje kvalitete u izvananalitičkoj fazi. Ujednačenost ukupne prosječne ocjene u različitim skupinama upućuje na činjenicu kako niti vrsta ustanove tj. laboratorija u kojoj medicinski biokemi-

lowest score being recorded for phlebotomy procedures (Table 3).

According to type of facility, no difference was observed in the score for questions regarding criteria of sample acceptance and results reporting, though a significant difference for questions regarding procedures of phlebotomy was observed ($P = 0.018$), where participants from primary health care laboratories (2.89 \pm 0.53), general hospital (2.66 \pm 0.34) and clinical hospital laboratories (2.64 \pm 0.31) had significantly lower scores than participants from private laboratories (3.20 \pm 0.37) (Table 3).

Criteria of sample acceptance score was significantly lower in group of medical biochemists with master degree than in those being specialists (3.26 \pm 0.46 vs. 3.43 \pm 0.51; $P = 0.039$) (Table 3).

No difference in any of the scores regarding information skills was observed. As regards the question concerning the procedure of recording nonconformities, 22% of participants did not record nonconformities properly (e.g., never or rarely), whereas 78% of participants recorded nonconformities often or always (Table 1).

Discussion

The overall score of 3.12 \pm 0.38 on a scale from 1 to 4 can be considered a reliable indicator of medium quality standards in our survey. The lack of difference in the overall score among the different groups also highlighted that type of laboratory, professional qualification and informatics skills of medical biochemists responsible for laboratory activity are not directly associated with the

TABLICA 3. Međusobna usporedba ocjena kriterija prihvatljivosti uzoraka, postupaka vađenja krvi i izvještavanja nalaza te ocjena tih postupaka s obzirom na vrst ustanove u kojima ispitanici rade, njihovu stručnu spremu i informatičku pismenost.

TABLE 3. Comparison of criteria of sample acceptance score, procedures of phlebotomy score and reporting of results score obtained through questionnaire between each other and between participants from different type of institution, professional qualification and their informatics skills.

Characteristics of participants		N (%)	Criteria of sample acceptance score $\bar{x} \pm SD$	Statistics	Procedures of phlebotomy score $\bar{x} \pm SD$	Statistics	Reporting of results score $\bar{x} \pm SD$	Statistics
All participants		144 (100)	3.33 \pm 0.49	-	2.83 \pm 0.46	-	3.19 \pm 0.48	F = 42.57^a P < 0.001
Type of institution	Primary health care	57 (40)	3.35 \pm 0.44	F = 1.69 P = 0.141	2.89 \pm 0.53	F = 2.84^b P = 0.018	3.25 \pm 0.44	F = 1.08 P = 0.375
	General hospital	21 (15)	3.10 \pm 0.58		2.66 \pm 0.34		3.01 \pm 0.59	
	Specialized hospital	19 (13)	3.38 \pm 0.48		2.80 \pm 0.44		3.22 \pm 0.47	
	Clinical hospital	17 (12)	3.45 \pm 0.42		2.64 \pm 0.31		3.08 \pm 0.55	
	University hospital	19 (13)	3.46 \pm 0.56		2.80 \pm 0.42		3.19 \pm 0.41	
	Private laboratories	10 (7)	3.23 \pm 0.43		3.20 \pm 0.37		3.31 \pm 0.45	
Professional qualification	M.Sc.	83 (58)	3.26 \pm 0.46	t = 2.08 P = 0.039	2.83 \pm 0.46	t = -0.08 P = 0.939	3.12 \pm 0.48	t = 1.88 P = 0.062
	Specialists	61 (42)	3.43 \pm 0.51		2.82 \pm 0.46		3.27 \pm 0.46	
Informatics skills	Good	89 (62)	3.36 \pm 0.49	t = -0.92 P = 0.362	2.83 \pm 0.46	t = -0.33 P = 0.746	3.23 \pm 0.44	t = -1.69 P = 0.093
	Medium	54 (38)	3.28 \pm 0.49		2.80 \pm 0.46		3.09 \pm 0.52	

^a All three groups are different from each other (post-hoc Student-Newman-Keuls test)

^b Participants from primary health care laboratories, general hospital and clinical hospital laboratories have significantly lower score than participants from private laboratories (post-hoc Student-Newman-Keuls test).

čari rade, njihova stručna sprema niti informatička pismenost nemaju utjecaj na kvalitetu izvananalitičke faze laboratorijske dijagnostike. Međutim, podijele li se tvrdnje u tri odvojene cjeline i izračuna li se za svaku podskupinu postupaka prosječna ocjena, pojavljuje se razlika među pojedinim skupinama. Prvi i najznačajniji rezultat je najniža ocjena za postupke vađenja krvi (2,83 \pm 0,46), za kojom slijedi ocjena postupaka prilikom izvještavanja nalaza (3,19 \pm 0,48), dok kriteriji prihvatljivosti uzoraka imaju najveću ocjenu (3,33 \pm 0,49). Sve tri ocjene se međusobno statistički značajno razlikuju.

Postupak vađenja venske krvi poznat je problem i izvor mnogih laboratorijskih nesukladnosti te najkritičnija točka u izvananalitičkoj fazi laboratorijskog rada (11-14). Uprkos značajnom napretku u posljednja dva desetljeća i usavršavanju pribora za vađenje krvi (pouzdana identifikacija bolesnika, kušalice s podtlakom, igle prilagođene vađenju krvi, itd) važno je naglasiti kako je postupcima vađenja krvi potrebno posvetiti posebnu pažnju i sustavan nadzor kako bi se spriječile pogreške. Laboratorijsko osoblje će vjerojatno činiti manje pogrešaka tijekom vađenja krvi od ostalog medicinskog osoblja koje vadi krv (npr. medicinske sestre i liječnici) (15) pa je stoga potreb-

quality of the extra-analytical phase of laboratory practice. However, when questions were further classified in three groups, some difference emerged. The first and the most indicative finding is that questions on procedures of phlebotomy achieved the lowest score (2.83 \pm 0.46); an intermediate score was observed for results reporting (3.19 \pm 0.48), whereas the highest score was recorded for criteria of sample acceptance (3.33 \pm 0.49), all these significantly differing the one from another.

The phlebotomy practice is a well known and recognized problem in published studies, as probably the most critical issue in extra-analytical phase (11-14). Despite significant improvements during last two decades in blood sampling equipments and procedures (positive patient identification, vacuum tubes for blood sampling, more convenient needles for phlebotomy etc.), it is still important to emphasize that procedures of phlebotomy need a further attention and a more careful and systematic supervision in order to prevent errors. Importantly, laboratory personnel might probably make fewer mistakes during phlebotomy than other non-laboratory personnel performing it (e.g. nurses, physicians) (15), so that it is essential to extend supervision and continuous education

no nadzor nad postupcima vađenja proširiti i izvan laboratorija na sve osobe i odjele koji su uključeni u postupak uzimanja uzoraka (12,13,15).

Zanimljivo je kako 63% ispitanika izjavljuje da se u njihovim laboratorijima prihvaćaju uzorci krvi izuzeti bolesnicima koji dolaze iz udaljenih krajeva, ako su natašte i u 11 sati ujutro. Kako bi bolesnika poštediti ponovnog dolaska u bolnički laboratorij u odgovarajuće vrijeme, osoblje često zanemari pravila dobre laboratorijske prakse i uzima uzorke u neprimjereno doba dana i u neprimjerenim uvjetima, uzrokujući time moguće pogreške u laboratorijskim nalazima, što utječe i na kvalitetu rada i na bolesnikovo zdravlje. Takvi milosrdni razlozi za vađenje krvi bolesnicima koji dolaze prekasno tijekom dana, nisu natašte ili predugo gladiju, razvidno nisu u korist bolesnika.

Iako 80% ispitanika navodi kako se bolesnika prilikom vađenja krvi uvijek pita kako se zove, samo 14% navodi kako se često ili uvijek utvrđuje stvarni identitet bolesnika potvrđen osobnim dokumentom (sa slikom) (Tablica 1.). Postupci potvrde identiteta bolesnika često nisu regulirani pravilima laboratorijske prakse, međutim pogrešna identifikacija izvor je teških pogrešaka. Objavljeno je nekolicina studija koje raspravljaju utvrđivanje identiteta bolesnika i donose podatke kako je pogrešna identifikacija bolesnika u sustavu zdravstvene zaštite glavni uzrok medicinskih pogrešaka (12,16,17). U razvijenim zemljama utvrđena je i uvedena procedura identifikacije bolesnika, primjerice u SAD bolnički bolesnici nose narukvice obilježene crtičnim kodom s pomoću kojeg se identificiraju, dok je u Švedskoj obvezno bilježenje nacionalnog jedinstvenog matičnog broja. Narukvice s crtičnim kodom riješile su problem identifikacije u bolnicama, međutim identifikacija u ambulantnim ustanovama s velikim brojem bolesnika kojima se dnevno vadi krvi i dalje je središnji problem i izvor medicinskih pogrešaka. Od krunske je važnosti uspostaviti pouzdan sustav identifikacije bolesnika, kako bi se spriječile nehotične zamjene ali i zlonamjerni pokušaji zamjene identiteta.

Sukladno našim rezultatima, u laboratorijima jedne trećine ispitanika ne pridaje se dovoljna pažnja bilježenju točnog vremena uzimanja uzorka. U takvim je slučajevima nemoguće provjeriti je li poštovano propisano vrijeme od vađenja krvi do izrade laboratorijske analize, što može učiniti neopaženima ozbiljne pogreške u mjerenju analita čija se koncentracija značajno mijenja s vremenom (npr. elektroliti, laktat, glukoza, itd). Vrijeme uzimanja uzorka se uzima i kao početna točka u određivanju ukupnog vremena potrebnog za analizu (engl. *turn-around time*, TAT), koji je jedan od važnih pokazatelja kvalitete u laboratoriju. Upravljanje kvalitetom u laboratoriju nije moguće ukoliko se TAT propisno ne prati (16,18).

Prosječna ocjena učestalosti postupaka vađenja krvi nije povezana sa stručnom spremom niti informatičkom pis-

outside the walls of the laboratory, to all the personnel involved in this activity (12,13,15).

Sixty three percent of biochemists report that blood samples are accepted in their laboratories from patients coming from distant destinations, after overnight fasting at 11 AM for routine analyses (table 1). To accomplish the patients, saving them another visit to hospital laboratory, personnel often contravene rules of good laboratory practice and take blood sample in improper time and causing possible erroneous results that might impact on both, quality and patient's health. Compassionate reasons for blood sampling from patients coming too late, fasting too long or not fasting at all are obviously not in patient's favor.

Although 80% of participants self-reported to ask patient's name prior to blood sampling, only 14% declared that patient identification is often or always verified with official (picture based) document (Table 1). The procedure of identity verification is often not regulated by guidelines of laboratory practice, but it still can be a serious source of errors. There are several studies published with discussion of patient's identity verification issue. Misidentification of patients is acknowledged as a major cause of medical errors (12,16,17). In several developed countries there is a well established procedure for patient identification, for example wearing bar-coded wristbands (16) in USA hospitals, or checking and recording national identification number in Sweden (15). Bar-coded wrist bands significantly reduced misidentification in hospitals, but problem of identification in high turnover phlebotomy services is still a central issue regarding medical errors (12,16,17). As such, it seems of pivotal importance to have reliable system of identity verification, to prevent incidental mismatch or even abusive attempt of switching identity.

According to our results, one third of the laboratories still do not pay attention on sampling time recording. As such, it would be impossible to check if a proper time to analyses has been respected, and serious errors can consequently occur for those analytes which concentration might significantly change even over shorter period of time (e.g., electrolytes, lactate, glucose, etc.). We thereby suggest that the time of sampling should be used as the starting point for recording the TAT (turn-around time), inasmuch as TAT is one of the important quality control indicators and it might be so impossible to introduce proper quality management when TAT is not appropriately recorded (16,18).

The score recorded for phlebotomy procedures is not apparently associated with professional qualification or informatics skills of biochemists, but it is instead with the type of institution. The highest score regarding procedures of phlebotomy is obtained from participants working

menosti ispitanika, međutim povezana je s vrstom institucije kojoj laboratorij pripada. Najveća ocjena postupaka vađenja krvi utvrđena je u ispitanika iz privatnih laboratorija ($3,20 \pm 0,37$), dok je prosječna ocjena ispitanika u svim drugim skupinama manja od 3 (Tablica 3.). Rezultat upućuje kako ispitanici iz privatnih laboratorija (7%) polažu više pažnje postupcima vađenja krvi od ostalih, dok su ocjene postupaka izvještavanja nalaza i kriterija prihvatanja uzoraka podjednake bez obzira na vrst ustanove (Tablica 3.). Privatni laboratoriji rade u sustavu otvorenog tržišta u uvjetima jake konkurencije, pa je za pretpostaviti da su posebice osjetljivi u postupcima u kojima sudjeluje njihova interesna skupina tj. bolesnici te im nastoje pružiti najbolje moguće uvjete i svakako izbjeći bilo kakvu potrebu za ponovnim uzimanjem uzoraka.

Izvjestavanje laboratorijskih nalaza glavni je skup postupaka poslijeanalitičke faze. Ocjena tih postupaka značajno je veća od ocjene za postupke vađenja krvi, međutim rezultati upućuju na potrebu daljnjeg poboljšavanja tog dijela laboratorijskog rada. Primjerice, gotovo će svi ispitanici žurno obavijestiti telefonski liječnika o kritičnim nalazima, međutim 40% ispitanika takav će postupak rijetko ili nikad propisno zabilježiti u laboratorijsku dokumentaciju. Takvo ponašanje sprječava sljedivost postupaka izvještavanja laboratorijskih nalaza, čime se onemogućuje i dokazivanje javljanja nalaza, ukoliko se za tim pokaže potreba i u slučaju pogrešnog zapisivanja nalaza od strane osobe koja nalaz prima. Od iznimne je važnosti da kritični nalaz primi osoba zadužena za brigu nad bolesnikom i da se provjeri točnost podataka koje ona zapisuje (16). Neriješeni telefonski pozivi drugi su najčešći izvor pogrešaka u izvananalitičkoj fazi (19). Može se smatrati kako postupci o kojima u laboratoriju ne postoje dokazi u obliku zapisa u propisanoj dokumentaciji, nisu niti učinjeni (20).

Ukoliko je krv u mokraći test trakom blago pozitivna, a u sedimentu nema eritrocita, ispravljanje nalaza test trake u negativan čini se često ili uvijek u laboratorijima četvrtine ispitanika. Taj postupak nema opravdanja, zbog mogućeg prisustva slobodnog hemoglobina i mioglobina u mokraći, što je klinički značajan nalaz bez obzira na odsutnost eritrocita u sedimentu mokraće.

Kriteriji prihvatljivosti uzoraka imaju najveću ocjenu i velika je većina ispitanika postigla visoku kvalitetu tog dijela prijeanalitičke faze. Zanimljivo je kako se prosječna ocjena kriterija prihvatljivosti uzoraka razlikuje između skupine specijalista medicinske biokemije i diplomiranih inženjera medicinske biokemije ($3,43 \pm 0,51$ naspram $3,26 \pm 0,49$, $P = 0.039$; Tablica 3.). Rezultat navodi na zaključak kako viši stupanj stručnog usavršavanja donosi i veću svijest o važnosti postupaka izvananalitičke faze, međutim vjerojatno je i da je veći dio specijalista medicinske biokemije uključen u pripremu za akreditaciju koja podrazumijeva strogu primjenu pravila dobre laboratorijske prakse i sustavno nadgledanje postupaka.

in private laboratories (3.20 ± 0.37), whereas all others obtained scores less than 3.0 (Table 3). Participants from private laboratories (7% of all participants) were obviously paying more attention to blood sampling than others, while scores for other procedures such as criteria for sample acceptance and results reporting were not significantly different between different types of facility (table 3). Private laboratories inherently work in open market, in strong competition, so that it can be assumed that they might be much more sensitive to blood sampling issues, where stakeholders (e.g., patients) are involved ensuring the highest possible comfort for patients and avoidance of any unnecessary sampling repetition.

Result reporting is considered to be the leading part of the post-analytical phase and despite of higher score than those of phlebotomy procedures it can and has to be further improved. Although almost all participants reported that they would promptly inform the requesting physician on critical values, 40% of them will never or rarely record that they reported result by phone. Such behavior prevents the tracing of the reports, and introduces a strong possibility that erroneous results can be written down and the impossibility to prove results reporting when requested or necessary. It is of outmost importance to record verbally reported results, and to be sure that the appropriate person receives and correctly notes information on critical result (16). Unresolved phone calls happen to be the second most frequent error in extra-analytical phase (19). Traditionally, actions which are not recorded might be actually claimed as not happened (20).

Correction of results for blood in urine obtained by urine strip test according to microscopic finding of erythrocytes in the urinary sediment is still performed by one quarter of participants. This procedure has no real justification due to possible presence of free hemoglobin or myoglobin in urine regardless of the presence of erythrocytes that is a clinically important finding.

Questions on criteria of sample acceptance achieved the highest score and the vast majority of participants handled this part of the pre-analytical phase satisfactorily. Interestingly, the score for sample acceptance criteria was significantly higher in a group of biochemists with specialization, rather than in those with master's degree (3.43 ± 0.51 vs. 3.26 ± 0.49 ; $P = 0.039$; table 3). It can hence be conceived that a higher level of professional qualification leads to major awareness of the importance of the extra-analytical phases, and there is also a possibility that they are involved in preprocesses for accreditation which includes strict supervision of all laboratory phases.

Our assumption that higher informatics skills will be associated with quality of extra-analytical procedures could not be confirmed. The majority of participants (62%) self-reported good informatics skills, and no participants

Naša pretpostavka kako će bolji stupanj informatičke pismenosti biti povezan s kvalitetom izvananalitičke faze nije potvrđena. Većina ispitanika (62%) ocjenjuje svoju informatičku pismenost dobrom, a nema ispitanika koji su naveli kako nemaju vještinu uporabe računala. Dob ispitanika također nije povezana s prosječnom ocjenom, što poriče hipotezu kako će stariji medicinski biokemičari biti popustljiviji u poštivanju pravila izvananalitičke faze laboratorijske djelatnosti od mlađih.

Temeljni i obvezni postupak u sustavu kontrole kvalitete jest zapisivanje svih nesukladnosti tj. nezgoda, incidenta i odstupanja od propisanog načina rada, posebice u izvananalitičkoj fazi u za to namijenjenu dokumentaciju. Još uvijek 6% ispitanika navodi kako se u njihovim laboratorijima nikada ne zapisuju nesukladnosti, u 16% se to čini rijetko, dok približno polovica ispitanika (46%, Tablica 1.) navodi kako to čini uvijek. Rezultat upućuje na činjenicu da polovica ispitanika nema uvid u pogreške koje se redovito događaju u njihovim laboratorijima. Ukoliko se želi uvesti kontrola nad procesima u laboratorijskoj dijagnostici, nužno je propisno bilježiti sve nesukladnosti te dokumentirati analizirati, kako bi se prepoznale pogreške i poduzele primjerene mjere za njihovo otklanjanje i sprječavanje ponovnog pojavljivanja (3,20,21).

Glavno ograničenje ovog istraživanja jest u osrednjem udjelu odgovora na anketni upitnik (27%). Pretpostavili smo kako je uzorak reprezentativan populaciji medicinskih biokemičara u Hrvatskoj, međutim ne može se isključiti pristranost koja proizlazi iz mogućnosti da su anketu ispunili visoko motivirani ispitanici s izraženim interesom za temu istraživanja, dok su se ispitanici s niskim interesom i stavom o maloj važnosti teme uzdržali od ispunjavanja.

Sljedeće ograničenje je povezano s načinom prikupljanja podataka anonimnim upitnikom. Svi rezultati i zaključci proizlaze iz odgovora ispitanika koji su ih dali prema vlastitoj procjeni. Potrebno je upozoriti i na mogućnost socijalno poželjnih odgovora ispitanika koji su opisivali poželjnu, a ne stvarnu učestalost pojedinih postupaka, bez obzira na zajamčenu anonimnost. Potrebno je uzeti i u obzir kako najveći dio ispitanika opisane postupke ne izvodi osobno, već je odgovorno i zaduženo za nadzor nad radom tehničkog osoblja koje postupke izvodi. Upitnik su u cijelosti oblikovali autori istraživanja pa on tako odražava naša stajališta, proizlazi iz vlastitog iskustva u radu u različitim laboratorijima u Hrvatskoj. S obzirom na to, prihvaćamo mogućnost kako su pojedini postupci kao pokazatelji kvalitete izvananalitičke faze precijenjeni ili podcijenjeni, što je moguća tema rasprave.

Rezultati istraživanja upućuju na zaključak kako je kvaliteta izvananalitičke faze laboratorijske dijagnostike u Hrvatskoj zadovoljavajuća, međutim ističu i žurnu potrebu za daljnjim unaprjeđivanjem, kako bi se dostigli standardi

reported poor skills. The age of participants was also not associated with the score, thus confuting the hypothesis that elderly participants might be more permissive to rules of extra-analytical phase than the younger ones.

The essential basis and mandatory request of quality control system of all phases, especially the extra-analytical ones, is the appropriate recording of all nonconformities. Still 6% of all participants never record nonconformities, 16% do that just rarely and half of them (46%, table 1) do it always. This revealed that half of participants are probably not aware of mistakes that regularly happen in their laboratories. All nonconformities have to be properly recorded in all cases to have a strict control of the processes, to recognize errors and to develop quality system and appropriate actions for correction and prevention of recurrences of similar events (3,20,21).

A major limitation in this study is the modest response rate (27%). Although we assume that the sample is still representative, it is possible that only participants with high interest and motivated have answered to the questionnaire, whereas those who did not find the study of importance did not, so that results might have been partially biased.

The other limitation is the possibility of socially desirable answers. As such, some participants might have reported desirable rather than true answers regardless of the anonymity of the survey (as previously highlighted results and conclusions are only based on self-reported data). An additional limitation is the fact that responders often do not perform some or even all of the described procedures themselves, but the laboratory technicians do so, the biochemists being only responsible for a global supervision of the activity. The questionnaire was completely designed by authors thus reflecting their attitudes and work experience in several different laboratories in Croatia. Considering that the importance of some items (e. g. described procedures) as quality indicators can be under or over estimated that can be subject of further discussion.

We can thereby conclude that results of quality of the extra-analytical phase of laboratory diagnostics in Croatia are satisfactory, but we also highlight the urgent need for further improvement, as in other countries. If high quality standards are to be reached, it is mandatory to supervise and record properly all laboratory procedures. If all procedures and nonconformities are not appropriately flowed and recorded, the laboratory management might not be aware of errors that can occur. With the clear perception that the vast majority of laboratory errors arise from the extra-analytical phase, further education of all the personnel involved, along with introduction of proper identification, recording, control and management of errors in the extra-analytical phase will improve laboratory pro-

razvijenih zemalja. Žele li se postići visoki standardi kvalitete, obvezno je nadzirati i dokumentirati primjereno sve laboratorijske postupke i procedure. Važno je naglasiti kako izočnost primjerenog i strogog dokumentiranja svih postupaka i nesukladnosti onemogućuje kvalitetno upravljanje laboratorijem, jer izvori pogrešaka ostaju neprepoznati. Sa sviješću kako velika većina laboratorijskih pogrešaka proizlazi iz izvananalitičke faze, daljnja izobrazba svog osoblja uključenog u laboratorijske postupke, zajedno s uvođenjem primjerenog prepoznavanja, dokumentiranja i uklanjanja pogreški, unaprijedit će značajno kvalitetu cjelokupnog laboratorijskog procesa. Preduvjet je postupcima certifikacije i akreditacije laboratorija prepoznati sve izvore pogrešaka i sustavno ih kontrolirati.

Zahvala

Zahvaljujemo Hrvatskoj komori medicinskih biokemičara na potpori istraživanju, pristupu adresama članova i tehničkoj i financijskoj potpori prilikom slanja upitnika poštanskim putem. Posebice zahvaljujemo svim članovima HKMB koji su ispunili i vratili upitnik te time pokazali interes i važnost poboljšanja kvalitete omogućivši provedbu ovog istraživanja.

cess and improve the quality of the total testing process. In this period, anticipating certification and accreditation, it is mandatory that all possible sources of errors come to the spotlight and that procedure for their recognizing, prevention and constant control are introduced.

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